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*LLC*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

JANSSEN PHARMACEUTICALS, INC.,  
JANSSEN PHARMACEUTICA NV,  
JANSSEN RESEARCH &  
DEVELOPMENT, LLC,

*Plaintiffs,*

v.

MYLAN LABORATORIES LIMITED, MYLAN  
PHARMACEUTICALS INC., and MYLAN  
INSTITUTIONAL LLC,

*Defendants.*

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT  
INFRINGEMENT**

**(Filed Electronically)**

Plaintiffs Janssen Pharmaceuticals, Inc. (“JPI”), Janssen Pharmaceutica NV (“JPN”), and Janssen Research & Development, LLC (“JRD”), (collectively “Plaintiffs” or “Janssen”), for their Complaint against Defendants Mylan Laboratories Limited (“MLL”), Mylan Pharmaceuticals, Inc. (“MPI”), and Mylan Institutional LLC (“MIL”) (collectively “Defendants” or “Mylan”), hereby allege as follows:

### **NATURE OF THE ACTION**

1. This is a civil action for infringement of United States Patent No. 10,143,693 (the “’693 Patent”).
2. This action relates to the submission of Abbreviated New Drug Application (“ANDA”) No. 216228 by Mylan to the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of JPI’s Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) prior to the expiration of the ’693 Patent.

### **THE PARTIES**

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
4. JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.
5. JRD is a limited liability company organized and existing under the laws of New Jersey, having its principal place of business at 920 Route 202 South, Raritan, New Jersey 08869.
6. On information and belief, MLL is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee

Hills, 500034, Hyderabad, India. Upon information and belief, MLL is an agent or affiliate of MPI and MIL.

7. On information and belief, MPI is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, MPI is an agent or affiliate of MLL and MIL.

8. On information and belief, MIL is a limited liability company organized and existing under the laws of Delaware, having a place of business at 4901 Hiawatha Drive, Rockford, Illinois 61003. Upon information and belief, MIL is an agent or affiliate of MLL and MPI.

9. On information and belief, MLL, MIL, and MPI are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

10. On information and belief, MLL, MIL, and MPI are wholly-owned subsidiaries of Viatris Inc., a corporation organized under the laws of Delaware, with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

11. On information and belief, MLL is acting on behalf of itself and on behalf of MPI and MIL with respect to Mylan's ANDA No. 216228.

### **JURISDICTION AND VENUE**

12. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

14. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

**MLL**

15. This Court has personal jurisdiction over MLL because, *inter alia*, MLL has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 216228, MLL will, directly or through its affiliates MPI and/or MIL, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in the United States, including in New Jersey, prior to the expiration of the '693 Patent.

16. Exercising personal jurisdiction over MLL in this district would not be unreasonable given MLL's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

17. This Court also has personal jurisdiction over MLL because MLL has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, MLL regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including MPI and MIL—including by selling pharmaceutical products in New Jersey. On information and belief, MLL derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

18. On information and belief, MLL, either directly or indirectly through MIL or MPI, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

19. This Court also has personal jurisdiction over MLL because, *inter alia*, this action arises from the actions of MLL directed toward New Jersey. For example, MLL's counsel sent a letter dated September 8, 2021 to JPI, a corporation with its principal place of business in this Judicial District, stating that MLL had submitted ANDA No. 216228 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) prior to the expiration of the '693 Patent. If MLL succeeds in obtaining FDA approval, it would sell its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in New Jersey and other states, either directly or through its affiliates MPI and/or MIL, causing injury to Plaintiffs in New Jersey.

20. MLL has agreed that, for purposes of this action only, it will not contest venue and jurisdiction in this Judicial District.

21. MLL has conceded that venue is proper over MLL in patent cases in this Judicial District in at least the following District of New Jersey action: *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals, Inc.*, Civil Action No. 18-cv-1430.

22. MLL has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals, Inc. et al.*, Civil Action No. 2:15-cv-8180; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 1:14- cv-7094; *Horizon*

*Pharma, Inc. et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 3:15-cv-3327; and *Astrazeneca AB, et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 3:13-cv-4022.

23. In the alternative, this Court has personal jurisdiction over MLL because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

**MIL**

24. On information and belief, MIL, either directly or indirectly through MLL and/or MPI, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

25. This Court has personal jurisdiction over MIL because, *inter alia*, MIL has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 216228, MIL will, directly or through its affiliates MPI and/or MLL, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in the United States, including in New Jersey, prior to the expiration of the '693 Patent.

26. Exercising personal jurisdiction over MIL in this district would not be unreasonable given MIL's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

27. This Court also has personal jurisdiction over MIL because MIL has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, MIL regularly and continuously transacts business within New Jersey, either directly or through its affiliates—

including MPI and MLL—including by selling pharmaceutical products in New Jersey. On information and belief, MIL derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

28. On information and belief, MIL has substantial, continuous and systematic contacts with New Jersey, is registered to do business in New Jersey, has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug manufacturer and wholesaler in New Jersey.

29. This Court also has personal jurisdiction over MIL because, *inter alia*, this action arises from the actions of MIL directed toward New Jersey, either directly or through MLL and/or MPI. For example, MLL's counsel sent a letter dated September 8, 2021 to JPI, a corporation with its principal place of business in this Judicial District, stating that MLL had submitted ANDA No. 216228 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) prior to the expiration of the '693 Patent. If MLL succeeds in obtaining FDA approval, MIL would sell its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in New Jersey and other states, either directly or through its affiliates MPI and/or MLL, causing injury to Plaintiffs in New Jersey.

30. MIL has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey action: *AstraZeneca Pharmaceuticals LP, et al., v. Mylan Institutional LLC*, Civil Action No. 1:16-cv-4612.

### **MPI**

31. On information and belief, MPI, either directly or indirectly through MLL or MPI, is in the business of formulating, manufacturing, marketing, and selling generic

prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

32. On information and belief, MPI has substantial, continuous, and systematic contacts with New Jersey, including, but not limited to, the direction of operation and management of MLL and MIL.

33. This Court has personal jurisdiction over MPI because, *inter alia*, MPI has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 216228, MPI will, directly or through its affiliates MIL or MLL, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in the United States, including in New Jersey, prior to the expiration of the '693 Patent.

34. Exercising personal jurisdiction over MPI in this district would not be unreasonable given MPI's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

35. This Court also has personal jurisdiction over MPI because MPI has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, MPI regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including MIL and MLL—including by selling pharmaceutical products in New Jersey. On information and belief, MPI derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.



36. On information and belief, MPI has substantial, continuous and systematic contacts with New Jersey, is registered to do business in New Jersey, has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug manufacturer and wholesaler in New Jersey.

37. This Court also has personal jurisdiction over MPI because, *inter alia*, this action arises from the actions of MPI directed toward New Jersey, either directly or through MLL and/or MIL. For example, MLL's counsel sent a letter dated September 8, 2021 to JPI, a corporation with its principal place of business in this Judicial District, stating that MLL had submitted ANDA No. 216228 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) prior to the expiration of the '693 Patent. If MLL succeeds in obtaining FDA approval, MPI would sell its proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) in New Jersey and other states, either directly or through its affiliates MLL and/or MIL, causing injury to Plaintiffs in New Jersey. Furthermore, upon information and belief, MPI is MLL's authorized agent with respect to ANDA No. 216228.

38. MPI has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Valeant Pharmaceuticals International, Inc. et al. v. Mylan Pharmaceuticals, Inc. et al.*, Civil Action No. 2:15-cv-8180; *Baxter Healthcare Corp., et al. v. Agila Specialties Private Limited, et al.*, Civil Action No. 1:14- cv-7094; *Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 3:15-cv-3327; *Astrazeneca AB, et al. v. Mylan Pharmaceuticals, Inc., et al.*, Civil Action No. 3:13-cv-4022; and *Janssen Products, L.P. et al. v. Lupin Limited, et al.*, Civil Action No. 2:10-cv-5954.

**MLL, MIL, and MPI**

39. On information and belief, MLL, MIL, and MPI, along with other subsidiaries of Viatris Inc., hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

40. On information and belief, MLL, MIL, and MPI employ people and maintain a regular and established office in New Jersey, including at least at 110 Allen Road, Basking Ridge, New Jersey 07920.

41. On information and belief, MLL, MIL, and MPI are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 216228.

42. On information and belief, MLL, MIL, and MPI are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 216228.

43. On information and belief, MPI and MIL, together with their affiliate and/or agent MLL, filed the Mylan ANDA with the FDA that is at issue in this patent infringement suit.

44. On information and belief, MLL, MIL, and MPI, alone and/or together with each other as affiliates and/or agents, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including JPI, which is a New Jersey company, in New Jersey.

**THE PATENT-IN-SUIT**

45. On December 4, 2018, the '693 Patent, titled "Dosing Regimen For Missed Doses For Long-Acting Injectable Paliperidone Ester" was duly and legally issued by the United States Patent & Trademark Office. JNV owns the '693 patent. A copy of the '693 Patent is attached as Exhibit A.

46. JPI holds approved NDA No. 207946 for paliperidone palmitate extended-release injectable suspension, which is prescribed and sold under the trademark Invega Trinza®.

47. Pursuant to 21 U.S.C. § 355(b)(1), the '693 Patent is listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering JPI's Invega Trinza® brand paliperidone palmitate extended-release injectable suspension products.

**COUNT I:  
INFRINGEMENT OF THE '693 PATENT BY  
MYLAN'S ANDA FOR INVEGA TRINZA®**

48. Plaintiffs re-allege paragraphs 1-47 as if fully set forth herein.

49. An actual controversy exists between the parties as to whether Mylan's proposed sale of its generic paliperidone palmitate extended-release suspension products (273 mg/0.875 mL and 410 mg/1.315 mL) infringe at least one claim, including claim 1, of the '693 Patent.

50. By letter dated September 8, 2021 ("Mylan Notice Letter"), MLL notified Plaintiffs that it had submitted ANDA No. 216228 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that ANDA No. 216228 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic paliperidone palmitate extended-release injectable suspension products prior to the

expiration of certain Orange Book listed patents. ANDA No. 216228 specifically seeks FDA approval to market generic versions of JPI's Invega Trinza® brand paliperidone palmitate extended-release injectable suspension products in the 273 mg/0.875 mL and 410 mg/1.315 mL strengths prior to the expiration of the '693 Patent.

51. ANDA No. 216228 includes a Paragraph IV Certification that the claims of the '693 Patent are invalid, unenforceable, and/or not infringed.

52. Upon information and belief, the Mylan Notice Letter was sent to Plaintiffs via overnight mail no earlier than September 8, 2021.

53. The Mylan Notice Letter was subsequently received by Plaintiffs, and Plaintiffs commenced this action within 45 days of the date of receipt of Mylan's Notice Letter.

54. The Mylan Notice Letter purports to include a Notice of Certification for ANDA No. 216228 under 37 C.F.R. § 314.95(c)(6) as to the '693 Patent. The Mylan Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '693 Patent.

55. Mylan has actual knowledge of the '693 Patent, as shown by the Mylan Notice Letter.

56. On information and belief, Mylan's proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL), if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '693 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

57. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim, including at least claim 1, of the '693 Patent by submitting, or

causing to be submitted, to the FDA ANDA No. 216228 seeking approval to manufacture, use, import, offer to sell or sell Mylan's proposed generic versions of Janssen's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) before the expiration date of the '693 Patent. Upon information and belief, the products described in ANDA No. 216228 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '693 Patent under 35 U.S.C. § 271(e)(2)(A).

58. On information and belief, physicians and/or patients will directly infringe at least one claim, including at least claim 1, of the '693 Patent by use of Mylan's proposed generic versions of Janssen's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) upon approval.

59. On information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's proposed generic versions of Janssen's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) by physicians and/or patients with the knowledge and intent that Mylan's generic products will be used by physicians and/or patients in a manner that infringes at least one claim, including at least claim 1, of the '693 Patent for the pecuniary benefit of Mylan. Pursuant to 21 C.F.R. § 314.94, Mylan is required to copy the FDA-approved Invega Trinza® labeling. Mylan specifically intends its generic paliperidone palmitate products to be used according to its proposed labeling in a manner that infringes at least one claim, including at least claim 1, of the '693 Patent. Upon information and belief, Mylan will thus induce the infringement of at least one claim, including at least claim 1 of the '693 Patent.

60. On information and belief, if the FDA approves ANDA No. 216228, Mylan will sell or offer to sell its proposed generic products specifically labeled for use in practicing at least one claim, including at least claim 1 of the '693 Patent, wherein Mylan's

proposed generic products are a material part of the claimed invention, wherein Mylan knows that physicians will prescribe and patients will use Mylan's proposed generic products in accordance with the instructions and/or label provided by Mylan in practicing at least one claim, including at least claim 1 of the '693 Patent, and wherein Mylan's generic paliperidone palmitate extended-release suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Mylan's proposed generic paliperidone palmitate extended-release suspension products are specifically designed for use in a manner that infringes at least one claim, including at least claim 1, of the '693 Patent. On information and belief, Mylan will thus contribute to the infringement of at least one claim, including at least claim 1 of the '693 Patent.

61. On information and belief, the actions described in this Complaint relating to Mylan's ANDA No. 216228 were done by and for the benefit of Mylan.

62. Plaintiffs will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

63. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

#### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs respectfully pray for the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Mylan has infringed at least one claim of the '693 Patent through Mylan's submission of ANDA No. 216228 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Mylan's proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL

and 410 mg/1.315 mL) identified in this Complaint in the United States before the expiration of the '693 Patent;

B. Enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Mylan's commercial manufacture use, offer for sale, or sale within the United States, or importation into the United States of Mylan's proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) identified in this Complaint, prior to the expiration of the '693 Patent, constitutes infringement of one or more claims of the '693 Patent under 35 U.S.C. § 271(a), (b), or (c);

C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 216228 be a date that is not earlier than the expiration date of the '693 Patent, or such later date as the Court may determine;

D. Order that Mylan, its affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Mylan, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Mylan's proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) identified in this Complaint, and any other product that infringes or contributes to the infringement of the '693 Patent, prior to the expiration of the '693 Patent, or such later date as the Court may determine;

E. If Mylan engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Invega Trinza® brand product (273 mg/0.875 mL and 410 mg/1.315 mL) identified in this Complaint prior to the expiration of the '693 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorneys' fees; and

G. Award such further and other relief that the Court deems proper and just.

Dated: October 14, 2021

s/ Keith J. Miller

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**LOCAL CIVIL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for *Janssen Pharmaceuticals, Inc. v. Mylan Laboratories Limited*, 3:20-cv-13103 (ZNQ-LHG), and *Janssen Pharmaceuticals, Inc. v. Mylan Laboratories Limited*, 3:21-cv-15137 (ZNQ-LHG).

Dated: October 14, 2021

s/ Keith J. Miller

Keith J. Miller

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